

# EXHIBIT

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

<b>In re: NATIONAL PRESCRIPTION OPIATE LITIGATION</b>	) ) ) ) )	<b>MDL NO. 2804</b>
<b>THIS DOCUMENT RELATES TO:</b> <i>“Case Track Three”</i>		<b>CASE NO. 1:17-MD-2804</b>
		<b>Judge Dan Aaron Polster</b>

**PROPOSED ORDER FOR INJUNCTIVE RELIEF**

**I. INTRODUCTION**

A. Within 90 days of the Effective Date of the Order (as defined in the Order, the “Effective Date”) (except where this Order specifies a different implementation period), Walmart, Walgreens, and CVS Pharmacy, Inc. (the “Defendants”) shall implement the terms set forth in this Order (the “Terms”).

B. To the extent that the Defendants already have in place committees, departments, policies or programs that satisfy the terms of this Order, no re-naming is required by this Order.

C. By separate order, the Court will appoint a Special Master to oversee the compliance with specific provisions of this Order.

D. Overview

1. The Defendants will implement or maintain a Controlled Substance Compliance Program (“CSCP”).

2. The CSCP must include written standard operating procedures and/or corporate policies (the “CSCP Policies and Procedures”) required by this Order.

3. The CSCP shall apply during the term of this Order to each of the Defendants’ retail pharmacy stores within the Counties of Lake and Trumbull.

4. The Defendants shall provide a copy of the relevant CSCP Policies and Procedures and objective monitoring tools and assessments to the Special Master within 90 days of the Effective Date. To the extent any implementation is expected to require additional time, the Defendants will advise the Special Master as to the reasons for the delay.

E. Compliance with Laws

1. The Defendants acknowledge and agree that their retail pharmacies must comply with applicable federal and Ohio state laws, including regarding the dispensing of Controlled Substances. The requirements of this Order are in addition to, and not in lieu of, any other requirements of federal or Ohio state law. Nothing in this Order shall be construed as relieving the Defendants of the obligation of their retail pharmacies to comply with all federal and Ohio state and local laws, nor shall any of the provisions of the Order be deemed as permission for the Defendants to engage in any acts or practices prohibited by such laws.

2. The Order is not intended to and shall not be interpreted to prevent the Defendants from taking or implementing any other compliance or policy steps necessary to address their retail pharmacies' conformity with local, state, and federal legal requirements.

3. In the event that the Defendants determine that there is a conflict between the Order and the requirements of federal, state, or local laws, such that the Defendants determine that they cannot comply with the Order without violating these requirements, the Defendants shall document such conflicts and notify the Counties and the Special Master that it intends to comply with the law to the extent necessary to eliminate the conflict. Within thirty (30) days after receipt of a notification from the Defendants referenced above, the Counties may request a meeting to discuss the conflict and the Defendants shall comply with any such reasonable request. In the event that the Defendants and the Counties cannot agree, they may seek relief and a final resolution from the Special Master. Nothing in this paragraph shall (i) limit the right of the Counties to disagree with the Defendants as to the impossibility of compliance and to seek to enforce the Order accordingly; or (ii) be deemed to relieve the Defendants from following any subsequently enacted law that is more restrictive than the provisions of the Order, or from following the Order if they are more restrictive than applicable laws, to the extent the Defendants can adhere to both the Order and the provisions of local, state or federal law.

4. In the event that the any action, administrative or otherwise, is commenced against the Defendants, any of their retail pharmacies, or their pharmacy personnel as a result of the Defendants' obligations under this Order in Lake or Trumbull counties—including but not limited to actions brought by State Boards of Medicine and Pharmacy or the State Department of Health—the Defendants may seek relief from the Special Master and the Court.

5. The Defendants shall retain all records it is required to create pursuant to their obligations hereunder in an electronic or otherwise easily accessible format for the term of this Order. Nothing in this Order shall waive any applicable privilege that may be asserted over any such record.

## **II. TERM AND SCOPE**

A. The term of the Order shall be ten years from the Effective Date, unless otherwise specified herein.

B. No later than 60 days before the conclusion of the ten year term, the parties shall submit a brief setting forth whether there is good cause to extend the provisions of this order for injunctive relief. No later than 30 days before the conclusion of the ten year term, the Special Master shall make a recommendation to the Court as to whether further injunctive relief is needed to further abate the public nuisance based on the Special Master's own observations and the submissions of the parties.

C. This Order shall apply to the Defendants' operation of any retail pharmacy store within the Counties of Lake and Trumbull that dispense Controlled Substances to Patients.

## **III. DEFINITIONS**

A. The term "Controlled Substances" means those substances designated under schedules II-V pursuant to the federal Controlled Substances Act and the laws and regulations of the State that incorporate the federal Controlled Substances Act.

B. The term "Designated Controlled Substances" shall include: (a) oxycodone; (b) hydrocodone; (c) hydromorphone; (d) oxymorphone; (e) morphine; (f) methadone; and (g) fentanyl.

C. The term "Prescriber" means any individual that has written a prescription, whether legally valid or not, that is presented to one of the Defendants' retail pharmacy stores in Lake and Trumbull Counties.

D. The term "Patient" means any individual who receives a prescription for a Designated Controlled Substance from a Prescriber, whether legally valid or not, and attempts to fill it at one of the Defendants' retail pharmacy stores in Lake and/or Trumbull Counties.

## **IV. CONTROLLED SUBSTANCE COMPLIANCE PERSONNEL**

A. The Defendants shall designate a Chief Controlled Substance Compliance Officer, or other appropriately titled position, to be a member of the Controlled Substance Compliance Committee (described below in Section VI), and to oversee a Controlled Substance Compliance Department and the Defendants' compliance with this Order. As used in this Order, the terms "Controlled Substance Compliance Committee" and "Controlled Substance Compliance Department" refer to the entity or entities, however titled, that carry out the functions required by this Order. Notwithstanding the preceding sentence, to the extent an existing position, committee or department carries out the functions required by this Order, any other functions undertaken by such position, committee or department shall not be subject to this Order or oversight by the Special Master pursuant to this Order. The position, committee and department discussed in this subsection and below may bear different names and need not be limited to the roles and functions set forth herein.

B. The Chief Controlled Substance Compliance Officer shall have knowledge of and experience with the laws and regulation of Controlled Substances.

C. The Chief Controlled Substance Compliance Officer shall provide at least quarterly reports to the Controlled Substance Compliance Committee (described below in Section VI) and the Special Master regarding the Defendants' compliance with this Order, including the implementation of any changes to the CSCP Policies and Procedures required by this Order.

D. Staffing levels of the Defendants' Controlled Substance Compliance Department shall be reviewed periodically, but at least on an annual basis, by the Defendants' Controlled Substance Compliance Committee, to assess whether such staffing levels are sufficient for the Controlled Substance Compliance Department to comply with this Order. This review shall include consideration of relevant developments in technology, law, and regulations.

E. Throughout the term of this Order, the Defendants shall maintain a telephone and email hotline(s) (the "Hotline") to permit employees and/or Patients to anonymously report suspected inappropriate or illegitimate dispensing, prescribing or diversion of Designated Controlled Substances, violations of the CSCP Policies and Procedures, this Order, the Defendants' company policy, or other applicable law. The Defendants shall publish their Hotline contact information to their employees and Patients in Lake and Trumbull Counties. The Defendants shall maintain for the duration of this Order a record of each complaint made to the Hotline regarding Designated Controlled Substances and documentation regarding any investigation or response to such complaints. Nothing herein shall require the Defendants to investigate a pharmacist's professional judgment to refuse a prescription that the pharmacist believes was prescribed or is being used for other than a legitimate medical purpose or that the pharmacist believes was not prescribed by an individual Prescriber acting in the usual course of his or her professional practice.

## **V. INDEPENDENCE**

A. The Defendants' Controlled Substance Compliance Department personnel, the pharmacy personnel who work at the Defendants' retail pharmacies within Lake and Trumbull Counties, and field personnel who supervise such pharmacy personnel (together, "CSCP Employees") shall not be compensated in whole or in part by commissions, bonuses, incentives or any other monetary or non-pecuniary benefit that depends in any part on revenue or profitability targets or expectations specific to sales of Controlled Substances. Nothing in this Order shall be interpreted to prevent compensation of employees based on Defendants' overall revenue; general sales volumes, profitability targets/expectations for enterprise-, or general pharmacy-wide sales; however, specific pharmacy store sales, profitability targets in Lake and Trumbull counties should be excluded from their compensation package.

B. No CSCP Employees may be terminated, suspended, threatened with or face any other negative employment consequence for failing to meet any revenue or profitability targets/expectations specific to sales of Controlled Substances.

C. To the extent necessary to comply with this section, the Defendants' Controlled Substance Compliance Committee shall review, modify, and implement any changes to policies

specific to the sale or dispensing of prescription medications, including but not limited to compensation and non-retaliation.

## **VI. OVERSIGHT**

A. To the extent not already established, within ninety (90) business days of the Effective Date, the Defendants shall establish a compliance committee, however titled, that includes representatives from their respective legal, compliance, pharmacy operations, and asset protection departments, however named, to provide oversight over the CSCP and its compliance with this Order. For the purposes of reference herein, this committee, however named, shall be referred to as the “Controlled Substance Compliance Committee.” The Defendants shall maintain their Controlled Substance Compliance Committee for the duration of the term of this Order. The Chief Controlled Substance Compliance Officer of the Defendants shall serve as Chair of the Controlled Substance Compliance Committee.

B. The Defendants’ Controlled Substance Compliance Committee shall have regular meetings during which the Chief Controlled Substance Compliance Officer shall report on, and the Controlled Substance Compliance Committee shall review, among other things, (a) the Prescription Validation Process, including the CSCP Policies and Procedures on identifying and resolving Patient, Prescriber and Prescription Red Flags; (b) the training required under this Order; (c) proactive due diligence and site visits; (d) the Prescriber Review Processes; (e) significant new national and regional diversion trends involving Controlled Substances; (f) the Defendants’ adherence to this Order and applicable laws and regulations; and (g) any technology, staffing, or other resource needs for the CSCP. The Controlled Substance Compliance Committee shall have access to all CSCP reports described in the following subsection.

C. On an annual basis, the Defendants’ Controlled Substance Compliance Committee shall provide a written report to the appropriate officers of the Defendants including but not limited to the President, Chief Financial Officer, Chief Legal Officer, and the Chief Compliance Officer, as well as the Special Master, outlining (a) the Defendants’ adherence to, and any deviations from, this Order; (b) the allocation of resources sufficient to comply with this Order; and (c) any revisions to the CSCP that the Controlled Substance Compliance Committee has approved. The Compliance Committee shall document in its minutes its review of the annual Controlled Substance Compliance Committee reports.

D. The Defendants, through their Controlled Substance Compliance Departments and Committees, shall, at least once every year, review and oversee any enhancements to the CSCP Policies and Procedures and systems for dispensing activity that the Controlled Substance Compliance Committee deems necessary.

E. The Defendants’ Controlled Substance Compliance Committee shall be responsible for the approval of all material revisions to the CSCP Policies and Procedures, provided that nothing herein shall prevent the Defendants from implementing changes to the CSCP Policies and Procedures pending such review and approval.

## **VII. MANDATORY TRAINING**

A. The CSCP Policies and Procedures shall be published in a form and location readily accessible to all pharmacy and compliance personnel at each of the Defendants' retail pharmacy stores in Lake and Trumbull Counties. Online availability is sufficient, so long as pharmacy and compliance personnel have access to a computer with access to the CSCP Policies and Procedures.

B. Within 90 days of entering this Order, to the extent not already in place, the Defendants shall implement policies and procedures requiring all CSCP Employees to complete trainings on the CSCP Policies and Procedures required under this Order, including with respect to the Prescription Validation Process and their corresponding responsibility.

C. On an annual basis for the duration of the Order, the Defendants shall test their CSCP Employees, and any contractors serving as pharmacists or pharmacy technicians in their retail pharmacies in Lake and Trumbull Counties, on their knowledge regarding CSCP Policies and Procedures required under this Order, including with respect to the Prescription Validation Process and their corresponding responsibility.

D. It shall be a part of the CSCP Policies and Procedures and all trainings of all CSCP Employees required under this Order that pharmacists shall refuse to dispense Controlled Substances that they believe were prescribed or are being used for other than a legitimate medical purpose or that they believe were not prescribed by an individual Prescriber acting in the usual course of his or her professional practice.

E. All trainings required under this Order shall also make clear that pharmacists will not be penalized in any way for refusing to fill prescriptions for Controlled Substances or for conducting Due Diligence the pharmacist deems necessary pursuant to their corresponding responsibility.

## **VIII. THE PRESCRIPTION VALIDATION PROCESS**

A. As part of their CSCPs, to the extent not already in place, the Defendants shall have a Prescription Validation Process in the CSCP Policies and Procedures, as further described and set forth in this section, that each pharmacist employed by the Defendants at a retail pharmacy in Lake and Trumbull Counties is directed to follow when dispensing a prescription for a Controlled Substance.

B. The Defendants' CSCP Policies and Procedures shall provide that a Red Flag will be considered "resolved" such that the prescription can be filled if, after further investigation as described below, and given other facts and circumstances surrounding the prescription, a pharmacist determines, in his or her professional judgment, that the facts that triggered the Red Flag do not lead him or her to believe that the prescription was written or is being submitted for an illegitimate medical purpose or outside the usual course of a Prescriber's professional practice.

C. The Defendants' CSCP Policies and Procedures shall provide that if a pharmacist identifies any "Patient Red Flags" associated with a Controlled Substance prescription (described in Section IX(A) below), before filling the prescription the pharmacist must resolve them and document the resolution as explained in Section VIII(F) below; and that the method of resolution



falls within the judgment of the pharmacist and may include reviewing the Patient's profile and history with the Defendants, calling the Prescriber or Prescribers if appropriate, speaking with the Patient if appropriate, calling on the pharmacist's pre-existing knowledge of the Patient or Prescriber, reviewing available PDMP data, and/or reviewing other data or information available to the pharmacist.

D. The Defendants' CSCP Policies and Procedures shall provide that, except as allowed by Ohio law, a pharmacist may only fill a Controlled Substance prescription electronically transmitted by a Prescriber for such drugs; that if the pharmacist identifies any other "Prescription Red Flags" (described in Section IX(B) below), the pharmacist must resolve them and document the resolution as explained in Section VIII(F) below; and that the method of resolution falls within the judgment of the pharmacist and may include reviewing the Patient's profile and history with the Defendants, calling the Prescriber or Prescribers if appropriate, speaking with the Patient if appropriate, calling on the pharmacists preexisting knowledge of the Patient or Prescriber, reviewing available PDMP data, and/or reviewing other data or information available to the pharmacist.

E. The Defendants must put in place, to the extent not already in place, systems at their retail pharmacies in Lake and Trumbull Counties to check the licensure status of a Prescriber of Controlled Substances through a regularly updated prescriber database, to the extent such information is reasonably available for such purposes. The dispensing system shall block a Controlled Substance prescription from being filled if the prescriber database check reflects a DEA registration or state license that has been suspended or revoked and likewise shall block from being filled under a Controlled Substance prescription written by a prescriber blocked by the Defendants under a prescriber review program. CSCP Policies and Procedures shall require that if a pharmacist identifies any Prescriber Red Flags (described in Section IX(C) below), the pharmacist must resolve them, and document the resolution as explained in Section VIII(F) below; and that the method of resolution falls within the judgment of the pharmacist and may include reviewing the Defendants' records regarding the Prescriber, calling the Prescriber if appropriate, speaking with the Patient if appropriate, calling on the pharmacist's pre-existing knowledge of the Patient or the Prescriber, reviewing available PDMP data, and/or reviewing other data or information available to the pharmacist.

F. The Defendants' CSCP Policies and Procedures shall provide that the identification and resolution of all Red Flags identified by the pharmacist must be documented and to provide a clear description of the red flag(s) and either (i) how the flag was resolved before the medication was dispensed, or (ii) the reasons why the pharmacist refused to dispense the medication. The documentation should provide sufficient details in order that any subsequent reviewer will have a clear understanding of how each flag was resolved for any review or inquiry for auditing or regulatory purposes. Any such records shall be maintained for the duration of this Order.

G. The Defendants' CSCP Policies and Procedures shall provide that, even if all Red Flags are resolved, a pharmacist shall reject a prescription if, in his or her professional judgment, he or she believes that it was written or is being submitted for other than a legitimate medical purpose and/or was written outside the usual course of an Individual Prescriber's professional practice.



## IX. RED FLAGS

A. Notwithstanding any other potential red flags that the Defendants may identify in their CSCP Policies and Procedures, the Defendants shall identify in their CSCP Policies and Procedures “Patient Red Flags” identified by the DEA and the State, including but not limited to:

1. A Patient seeks to fill a Designated Controlled Substance prescription more than three days prior to the contemplated exhaustion date of an earlier prescription of the same Designated Controlled Substance;
2. A Patient seeks to fill Designated Controlled Substance prescriptions from more than three Prescribers, from separate practices, in a given 6-month period;
3. A Patient resides more than 25 miles from the Defendants’ retail pharmacy where the Designated Controlled Substance prescription is submitted;
4. A Patient resides more than 25 miles from the prescriber’s office.
5. A patient is seeking to fill a controlled substance prescription from three or more pharmacies.
6. A patient was dispensed an opioid and paid in cash even though the patient has insurance;

B. Notwithstanding any other potential red flags that the Defendants may identify in their CSCP Policies and Procedures, with respect to any Controlled Substance prescriptions, the Defendants shall identify in their CSCP Policies and Procedures the following potential “Prescription Red Flags:”

1. A prescription that fails to meet the requirements of law, *e.g.*, OH. STAT. § 3719.06.
2. A prescription that appears altered;
3. A prescription written with misspellings suggesting the prescription may not have been written by a Prescriber;
4. A prescription using atypical abbreviations suggesting the prescription may not have been written by a Prescriber; and
5. A prescription written with multiple colors of ink or in multiple different handwritings.

C. Notwithstanding any other potential red flags that the Defendants may identify in their CSCP Policies and Procedures, with respect to any Prescriber of Controlled Substances, the Defendants shall identify in their CSCP Policies and Procedures the following potential “Prescriber Red Flags:”

1. A Prescriber provides a Patient with prescriptions in combination with other Designated Controlled Substance prescriptions that present a serious risk to the patient or lack a legitimate medical purpose. Examples may include doses of over 90 MME a day in excess of CDC recommended doses or prescribing an opioid and a benzodiazepine together or prescribing over 210 days of supply of opioids in a six-month period.

2. A prescriber prescribes the same medication, with the same directions, for the same quantity for four or more individuals.

3. A Prescriber has no office within 25 miles of the retail pharmacy store.

## **X. UTILIZATION OF DATA**

A. The Defendants shall create an internal process that utilizes dispensing data, patient data and prescriber information (licensure status, prescribing patterns, prescribing statistics) to identify and update red flags, communicate and train pharmacists on the updated information, and revise policies & procedures to reflect the revised or new red flags.

B. The Defendants shall provide critical data to pharmacists as part of the dispensing process. The Pharmacies should integrate into their pharmacy management software tools designed to fight prescription drug abuse such as NARxCHECK, which has been integrated into proprietary pharmacy management systems such as QS/1, to assist pharmacists in the Defendants' retail pharmacies to analyze a patient's prescription profile against red flags and various PDMPs and allow pharmacists in the retail pharmacies to determine whether a patient might be obtaining prescriptions for controlled substances that have the potential for abuse or diversion. The integration as part of the dispensing process would provide an invaluable risk assessment to reduce inappropriate access to opioids, improve patient safety and prevent addiction and abuse of prescription drugs.

## **XI. REFUSALS TO FILL**

A. The Defendants shall develop a program designed to specifically manage and report Designated Controlled Substance prescriptions that have been refused for fill. The Defendants should require that when one of their pharmacists makes a determination to refuse to fill a Designated Controlled Substance prescription that determination should be documented within the electronic management system to be immediately visible and available to all pharmacists in the Defendants' retail pharmacies as well as reported to the Controlled Substance Compliance Committee, DEA, and State authorities. The Controlled Substance Compliance Committee shall review and analyze the information and report its findings to the Defendants' retail pharmacies in a manner that alerts all pharmacists in the retail pharmacies.

## **XII. PRESCRIBER and PATIENT REVIEW**

A. To the extent not already in place, the Defendants shall develop a process by which they regularly review the prescribing patterns and practices of Prescribers of Designated Controlled Substances (the “Prescriber Review Process”). The Prescriber Review Process shall employ algorithms, or other means, to review the Defendants’ retail dispensing data for potential Prescribers of concern. Once the Defendants identify through their process a Prescriber for further investigation, the review of a Prescriber shall include review of his or her prescribing as contained in the Defendants’ data and available licensing and disciplinary history. They may also include internet searches, interviews, and other information gathered in the discretion of the employees operating the Prescriber Review Process.

B. If after the Prescriber Review Process the Defendants have not resolved their concerns of illegitimate prescribing, then Controlled Substance prescriptions written by the Prescriber shall be blocked from being filled by the Defendants’ retail pharmacies in Lake and Trumbull Counties, with an opportunity at the discretion of the Defendants for the Prescriber to seek future reinstatement by providing information to the Defendants that may resolve their concerns. This block shall be on top of and in addition to any block based on a Prescriber’s licensure. On written demand of the Special Master or the Counties the Defendants shall provide the names of the prescribers who it has identified for investigation and/or whose prescriptions it has blocked.

C. To the extent not already in place, the Defendants shall develop a process by which they regularly review the Designated Controlled Substance prescriptions dispensed to certain Patients (the “Patient Review Process”). The Defendants shall employ algorithms, or other means, to review the Defendants’ retail dispensing data for potential Patients of concern. Once the Defendants identify through their process a Patient for further investigation, the review of a Patient shall include a review of his or her prescription history as contained in the Defendants’ data. They may also include internet searches, interviews and other information gathered in the discretion of the employees operating the Patient Review Process.

D. If after the Patient Review Process the Defendants have not resolved their concerns of potential abuse, misuse, or diversion, Defendant shall contact the Patient’s Prescribers, share their concerns with a Prescriber and refuse to fill controlled substance prescriptions for the Patient.

E. Defendants shall provide direct and timely responses to concerns raised by their pharmacists as to Patients and Prescribers of concern. In addition, each Defendant shall provide critical data to all of its pharmacists related to Patients and Prescribers of concern, in their area. Data related to Prescribers of Concern may include those Prescribers whose prescriptions are in the top percentiles for volume of controlled substances, share of controlled versus non-controlled drugs, and red flags. For Patients, it may include excessive doses, doctor or pharmacy shopping and/or behavior indicative of abuse, misuse or diversion.

### **XIII. PROACTIVE DUE DILIGENCE AND SITE VISITS**

A. During the term of this Order, the Defendants shall conduct periodic proactive compliance reviews of their retail pharmacy stores in Lake and Trumbull Counties to assist with the identification of potential compliance issues related to the dispensing of Designated Controlled Substances at their retail pharmacy stores in the Counties. This may be satisfied by the use of algorithms, or other electronic means, to analyze data associated with each pharmacy to identify particular pharmacies for review. Documentation of any resulting reviews shall be maintained by the Defendants and made accessible to all Controlled Substance Compliance Department personnel upon request for the duration of this Order.

B. During the term of this Order, the Defendants' field personnel shall also conduct site visits to each of their retail pharmacy stores in Lake and Trumbull Counties each year for the duration of the Order. Operating procedures shall specify that any concerns identified with the dispensing of Designated Controlled Substances shall be reported to the Controlled Substance Compliance Department. The Controlled Substance Compliance Department shall maintain resolution and documentation of any such reported concerns.

C. During the term of this Order, to the extent not already in place, the Defendants shall put in place processes to oversee inventory, record keeping, and theft and loss prevention controls at their retail pharmacy stores in Lake and Trumbull Counties.

D. The CSCP Policies and Procedures shall require that site visit reports, if any, related to the dispensing of Designated Controlled Substances shall be maintained by the Defendants and provided to all Controlled Substance Compliance Department personnel for the duration of this Order and an annual report shall be provided to the Special Master.

### **XIII. CONTROLLED SUBSTANCE DISPOSAL**

A. The Defendants' retail pharmacies in Lake and Trumbull Counties shall make available or display information to all Patients receiving a Designated Controlled Substance about the need to dispose and the proper disposal of unused Controlled Substances and the availability of disposal boxes, pouches or containers for purchase from the Defendants, or other products commercially manufactured to allow for the safe disposal of Controlled Substances and medications at home.

B. At each of their retail pharmacies in Lake and Trumbull Counties, the Defendants shall make available to Patients at its actual cost (per generally accepted accounting principles) a pouch or other container or product commercially manufactured to allow for the safe disposal of Controlled Substances and medications at home. The Defendants shall maintain sufficient written documentation supporting its actual cost for the duration of this Order.

#### **XIV. NALOXONE DISPENSING**

A. To the extent not already in place, the Defendants agree to obtain a non-patient-specific standing order covering each of their retail pharmacies in Lake and Trumbull Counties allowing for the dispensing of naloxone or other overdose reversal medications to the fullest extent allowable under Ohio law.

B. To the extent that Lake and Trumbull Counties and/or the State of Ohio obtain or enter into an agreement with a manufacturer of naloxone or other overdose reversal medication to provide naloxone or an overdose reversal medication to the Counties and/or State for free or at cost, the Defendants agree to dispense that naloxone or other overdose reversal medication at its actual cost for dispensing that naloxone or other overdose reversal medication (time and expense). Upon request by the Counties and/or State to dispense such medication, in the course of arranging logistics with the Counties and/or State, the Defendants shall provide the Counties and/or State with their calculation of the actual cost to dispense.

#### **XV. FRAUD, THEFT AND LOSS PREVENTION**

In addition to complying with all fraud, theft and loss procedures, policies and precautions required by state and federal law, the Defendants shall maintain information regarding the receipt and disposition of inventory of all Designated Controlled Substances for each retail pharmacy in Lake and Trumbull Counties.

#### **XVI. REPORTING TO LAW ENFORCEMENT**

To the extent not already in place, the Defendants shall implement standard operating procedures directing their employees to report any confirmed forged prescriptions to state or local law enforcement authorities within 7 days of completing any review of such prescription or conduct. The Defendants shall keep a record of all forged prescriptions in their database accessible to all pharmacists in the area and shall track all reports made to the DEA, local law enforcement and state agencies concerning Designated Controlled Substances. The Counties shall provide appropriate contact information for such reports. The Defendants shall comply with all statutes and regulations requiring the reporting of thefts and losses of Controlled Substances.

#### **XVIII. ENFORCEMENT OF ORDER TERMS**

A. Notice of Potential Violations and Opportunity to Cure.

1. A "Potential Violation" occurs when the Special Master determines, after appropriate investigation and due diligence, that the Defendants are not in substantial compliance with a material aspect of this Order. A Potential Violation may be for a single retail pharmacy.

2. Potential Violation Discovered by Counties or the Special Master.

- a. In the event a Potential Violation is identified by the Counties, the Counties shall notify the Defendants and the Special Master in writing (the “Counties’ Notice”).
- b. In the event a Potential Violation is identified by the Special Master, the Special Master shall notify the Defendants and the Counties in writing (the “Special Master Notice”).
- c. Within thirty (30) days of receipt of the Counties’ Notice or Special Master Notice, the Defendants shall provide a written response. The response shall include the Defendants’ position as to the act(s) of non-compliance with this Order’s Terms, including, possibly, a statement setting forth why the Defendant believes it is in substantial compliance with the relevant provision(s) or a statement explaining how the Potential Violation has been addressed.
- d. If the Counties and/or the Special Master wishes to meet with the Defendants, the Defendants shall promptly make itself available for such a meeting.

3. If, after review of a written response and any meeting, the Counties or the Special Master believe that a Potential Violation is ongoing or has not been substantially addressed, it will provide written notice to the Defendants and work in conjunction with the Defendants to devise, within thirty (30) days, a corrective action plan (“Corrective Action Plan”) to remedy such Potential Violation, including a reasonable period for implementation of such plan.

4. Within 60 and 120 days after implementing the Corrective Action Plan, the Defendants will provide a written compliance update to the Counties and the Special Master and make itself available to meet if requested. If after reviewing the compliance update and any meeting, the Counties believe a Potential Violation remains ongoing or has not been substantially addressed, the Counties may seek to enforce this Order before the Special Master and may take whatever action it deems necessary, including but not limited to bringing an action to enforce the Order, filing a new action (administrative or civil action) for violation of the Order as allowed by Ohio law, conducting further investigation, or attempting to negotiate an updated Corrective Action Plan with the Defendant. In the event the Special Master believes that a Potential Violation remains ongoing or has not been substantially addressed, the Special Master may order compliance with this Court’s Order and may award any other relief permitted by law.

5. If a Defendant fails or refuses to provide a written response, to devise or implement a Corrective Action Plan or to provide a compliance update as required by subsections A(2), A(3) and/or A(4), the Special Master may order compliance with this Court’s Order and may award any other relief permitted by law. In the alternative, the Counties may bring an action to enforce this Order, file a new action (administrative or civil

action) for violation of this Order as allowed by Ohio law, conduct further investigation, or attempt to negotiate an updated Corrective Action Plan with the Defendants.

6. If, after review of a written response and any meeting, pursuant to subsection A(2) or A(3), above, the Counties or Special Master concludes that a Potential Violation is not ongoing or has been substantially addressed, the Counties and/or Special Master will provide written notice of this conclusion to the Defendants within 30 days of reaching their conclusion.

7. Any party may appeal a decision from the Special Master to the Court for a final decision pursuant to Fed. R Civ. P. 53(f).

B. Enforcement Action. Prior to taking any court or administrative action, other than an action that the Counties or Special Master concludes is necessary to address an immediate threat to the health, safety, or welfare of the citizens of the Counties, or that a public emergency requiring immediate action exists, it will follow the process outlined above. If the Counties or Special Master conclude that action is necessary to address an immediate threat to the health, safety, or welfare of the citizens of the State or that a public emergency requiring immediate action exists, it will make best efforts to provide reasonable notice to the Defendants prior to initiating any such action.

#### **XIV. COMPLIANCE CERTIFICATION**

A. The Defendants' Chief Controlled Substance Compliance Officer shall, after diligent inquiry, complete an annual compliance certification.

B. The certification shall be provided to the Special Master annually for the duration of this Order.

C. The certification shall state:

"I understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include promoting compliance with regard to the [insert name of department] with all applicable statutory requirements, obligations of the Order, and applicable policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] is in compliance with the obligations of the Order. I understand that this certification is being provided to and relied upon by the U.S. District Court for the Northern District of Ohio."

D. If the Chief Controlled Substance Compliance Officer is unable to provide such a certification, he or she shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above to the Special Master.

E. Nothing in this Order shall be interpreted to abrogate the Defendants' applicable privileges or protections from disclosure, including without limitation those related to the attorney-



client privilege, the attorney work product doctrine, and the patient-safety work product privilege. Nothing in this Order shall require the Defendants to provide or produce any such privileged or protected materials.

#### **XVII. RECORDKEEPING**

The Defendants shall retain records they are required to create pursuant to their obligations hereunder in an electronic or otherwise readily accessible format. In addition to the prescription data regularly provided to the State of Ohio through its prescription drug monitoring program and all of the other records to which the State of Ohio has access under its pharmacy regulations, including without limitation through its on-site inspections of retail pharmacies, Lake and Trumbull Counties shall have the right to review the CSCP Policies and Procedures discussed herein. Nothing in these terms shall prohibit Lake and Trumbull Counties from issuing a lawful subpoena for records pursuant to an applicable law.

#### **XVIII. CHANGES AND MODIFICATIONS**

Nothing in this Order shall be construed to prohibit the Defendants from implementing improvements or enhancements or from otherwise evolving their systems and practices.